

235.35**Infant Formula Overview****Definitions**

Introduction This policy defines the categories of infant formula.

Definition: infant formula Infant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 USC 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 USC 350a) and the regulations at 21 CFR parts 106-107.

Issuance of formulas Local agencies must issue as the first choice of issuance the primary contract brand infant formula to the majority of healthy full-term infants. A contract brand infant formula (defined as contract non-exempt) that does not meet minimum requirements and specifications established in Table 4 of Section 246.10(e)(12) of Federal WIC regulations may be authorized for use with medical documentation.

Categories The categories of infant formulas and their definitions are listed below.

Category	Definition	Examples
Primary contract formula	The specific infant formula for which manufacturers submit a bid to the State Agency in response to a rebate solicitation and for which a contract was awarded by the State Agency as a result of that bid	<ul style="list-style-type: none"> • Gerber Good Start Soy • Similac Advance Stage 1
Contract Non-Exempt	A contract infant formula that does not meet the minimum requirements and specifications as outlined in the Federal WIC regulations	<ul style="list-style-type: none"> • Similac Sensitive • Similac for Spit Up • Similac Total Comfort

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Definitions, Continued

Categories (continued)

Category	Definition	Examples
Exempt	An infant formula that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems	<ul style="list-style-type: none"> • Similac Expert Care Alimentum • Nutramigen • Pregestimil • Neocate Infant • Formulas for inborn errors of metabolism • Premature formulas
Non-contract	All infant formulas, including exempt infant formula, that are not covered in the current infant formula cost containment contract	<ul style="list-style-type: none"> • Enfamil A.R. • Enfamil Premium Infant • Enfamil Gentlease • Similac Soy Isomil • Enfamil ProSobee • Private label infant formulas

Policy references

WC-04-34-P: Implementation of the Infant Formula Cost Containment Provisions of Public Law 108-265

WIC Policy Memorandum #2014-1 Changes to Abbott Infant Formula Product Line

WIC Policy Memorandum #2014-1A Clarification on Medical Documentation for Infant Formula Issued in Food Packages I and II